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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,909	11/16/2001	Joan M. Fallon	8016-5	3427

7590 04/23/2003

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1548

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/990,909

Applicant(s)

FALLON, JOAN M.

Examiner

Zachariah Lucas

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7 and 21-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,2,7,21-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other:

DETAILED ACTION

Status of the Application

1. Claims 1, 2, 7, and 21-29 are pending in the present application. In the prior action, claims mailed on July 30, 2002, claims 1-7 were pending, under consideration, and rejected, and claims 8-20 were pending and withdrawn from consideration as drawn to non-elected inventions. The claims elected invention were drawn to methods of determining whether a person has, or is likely to develop a disease by detecting a specific pathogen in a stool sample from the person. The originally filed claims were restricted in to two Groups, 1) the methods described above, and 2) biological markers for determining if an individual has a disease or disorder. These Groups were further divided according to the specific pathogen being screened for.

2. The reply filed on February 7, 2003 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s): the claims have been rewritten such that they now read on new subject matter, not originally claimed, and not part of the elected invention. See 37 CFR 1.111, and MPEP § 714.19. Since the above-mentioned reply appears to be *bona fide*, applicant is given **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

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3. The newly amended and added claims read on methods for determining if a person has, or is likely to develop a specific disease, by detecting in a stool sample from the person a plurality of different antigens associated with a plurality of different pathogens. Because the claims are no longer drawn to inventions of detecting a disease associated with a specific pathogen, but is now drawn to methods of detecting specific diseases or disorders by detecting a plurality of pathogens, the claims are now drawn to a new invention. In view of these amendments, the applicant may either 1) elect one of the new inventions as described below, with the understanding that any rejection made on the new claims will be considered to be necessitated by amendment or 2) amend the claims to conform with the originally elected invention.

Election/Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1, 2, 7, and 21-23, drawn to methods of determining if a person has, or can develop a PDD, classified in class 435, subclass 5.
 - II. Claims 24-26, drawn to methods for determining if a person has or can develop Parkinson's disease, classified in class 435, subclass 5.
 - III. Claims 27-29, drawn to methods of determining if a person has or can develop a Dysautonomic disorder, classified in class 435, subclass 5.

For Group I above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-III, and, if Group I is elected, election is also required to one of inventions (A)- (C).

- (A) The invention of Group I wherein the PDD is autism;
- (B) The invention of Group I wherein the PDD is ADD; and
- (C) The invention of Group I wherein the PDD is ADHD.

The inventions are distinct, each from the others, for the following reasons:

5. The inventions of Groups I-III, and of Groups (A)-(C) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions each relates to the detection of, or the detection of a future potential for, a different disease or disorder. As each of the methods relates to the detection of a different disease, therefore performing a different function, the inventions are distinct.

6. Because these inventions are distinct for the reasons given above because of recognized divergent subject matter, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

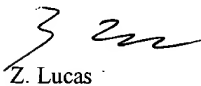
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Conclusion


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Z. Lucas
Patent Examiner
April 14, 2003



JAMES HOUSEL 4/21/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600